

December 23, 1998



Regulatory Branch
Division of Programs & Enforcement Policy
Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

2366 '99 JAN -5 P2:16

Attention : Consumer Safety Officer

RE: Trinovin™: Statements of Nutritional Support

To whom it may concern:

Pursuant to the requirements of the Dietary Supplement and Health Education Act of 1994, this letter is to notify the Food and Drug Administration that our company Novogen, Inc. of 6 Landmark Square, Stamford, Connecticut has in the last 30 days begun marketing its Trinovin™ brand dietary supplement of standardized red clover extract containing isoflavone plant compounds (daidzein, genistein, biochanin, formononetin), with the following labeling statements characterizing the mechanism by which such nutrients act to maintain human body structure or function, or describe general well-being from the consumption of these nutrients:

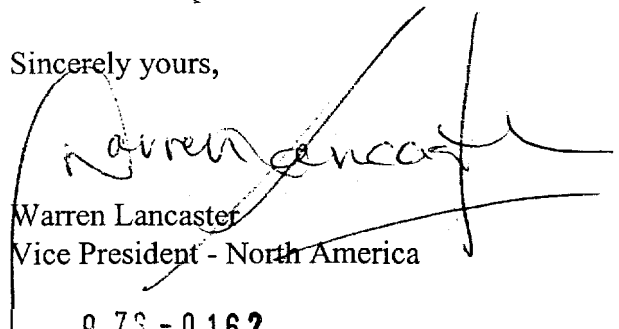
“Trinovin – Natural isoflavones to promote healthy prostate and urinary function.”

“Trinovin – Promotes prostate health naturally.”

“Trinovin is a natural isoflavone dietary supplement that can assist in normal prostate health, urinary flow, and quality of life of men, particularly those over 50 years of age.”

“The body of scientific evidence about the importance of isoflavone plant compounds to human health is growing rapidly. Dietary isoflavones are found in legumes such as clover, beans, and soy. Men who live in Asian, Central American, and Mediterranean countries traditionally consume vast amounts of isoflavone-rich food. They are far more likely to maintain normal prostate and urinary health later in life when compared to “western men”.”

Sincerely yours,


Warren Lancaster
Vice President - North America

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